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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,591	12/05/2001	Katherine S. Bowdish	ALEX-P01-055	3521
28120 7590 04/25/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER SCHLAPKOHL, WALTER	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 04/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/006,591

Applicant(s)

BOWDISH ET AL.

Examiner

Walter Schlapkohl

Art Unit

1636

*WLF*

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-6, 23, 24, 26-37, 73, 74 and 85-104.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_

*David J. [Signature]*  
DAVID J. [Name]  
PATENT EXAMINER

Continuation of 3. NOTE: Applicant's amendment introduces a limitation into the claims which was not previously presented. Specifically, Applicant has amended claims 1, 23, 33-36, 85 and 92 to recite "anneals specifically" in place of "are capable of annealing," "is capable of annealing," or "being capable of annealing." Furthermore, Applicant's amendment introduces a limitation into claim 1 with regard to the 20 nucleotides which separate the primer and collar sequences; this limitation was not previously presented. Because Applicant's amendment introduces new limitations into the claims, the amendment raises new issues with regard to search and consideration. Moreover, Applicant has introduced a limitation into claim 1 which specifies that the primer and collar sequences of the claimed plasmid do not specifically anneal to the at least 20 nucleotides which separate the portions of the polypeptide encoding sequence to which they anneal. This amendment raises the issue of new matter because the specification does not appear to provide sufficient landmarks nor direction for the instant limitation as claimed.

Continuation of 11. does NOT place the application in condition for allowance because: The amendment of the claims to recite "anneals specifically" in place of "are capable of annealing," "is capable of annealing," or "being capable of annealing" is not sufficient to overcome the rejection of the claims under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as vague and indefinite. The specification does not provide sufficient guidance with regard to the extent or nature of sequences which anneal "specifically." For example, does Applicant intend primer and/or collar sequences in which 50% of the nucleotides in said sequence are complementary upon annealing, and therefore that there is "correct base pairing" (see page 9, bottom, of the Remarks filed 4.2.2007); or does Applicant intend only sequences which are 100% complementary upon annealing? Furthermore, while Applicant argues that one of skill in the art understands that "specifically" means there is correct base pairing (ibid), Examiner disagrees. Indeed, one of skill in the art would understand that specific annealing can take place under various conditions, some of which require greater accuracy with regard to base pairing than others, i.e., levels of higher or lower stringency.

With regard to the rejection of claims under 35 U.S.C. 112, first paragraph (new matter) of record, Applicant's arguments are not found persuasive because Applicant's arguments rely upon portions of the specification which provide support only for primers which range "from about 10 nucleotides to about 50 or more nucleotides in length"; there is no support for a range of "at least 10 nucleotides." Furthermore, Applicant's arguments with regard to the rejection of the claims under 35 U.S.C. 112, first paragraph, written description are found unpersuasive because amendment of the claims to recite primer and collar sequence which "specifically" anneal during a polymerase reaction to a first and second portion of a polypeptide encoding portion of a nucleic acid does not narrow the genus of encompassed plasmids enough to show that Applicant was in possession of the claimed invention. Arguments drawn to a strong presumption that a specification as filed provides adequate written description support for the claimed invention and that "rejection of an original claim for lack of written description should be rare" do not address the deficiencies in the specification or the prior art which Examiner has set forth in the Office action mailed 4/18/2006. Furthermore, Applicant's assertion that rejection of an original claim for lack of written description should be rare is found unpersuasive because the claims currently rejected under 35 U.S.C. 112, first paragraph, are not original claims. While Examiner agrees with Applicant insofar as the level of skill in the art with regard to plasmid construction and targeting is high, this argument also fails to address the deficiencies in the specification and the prior art as set forth in the Office action mailed 4/18/2006. Exemplification of primer and collar sequences which anneal to different portions of antibody-encoding sequences, in light of the other factors pertinent to the rejection (disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation and/or any combination thereof), does not reasonably convey to one skilled in the relevant art that Applicant had possession of the claimed genus of plasmids.